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DK

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/928,757 09/12/97 MAERTENS G 1487-17

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HM12/0224

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EXAMINER

ZEMAN, M

ART UNIT	PAPER NUMBER
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1631

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DATE MAILED:

02/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/928,757

Applicant(s)

MAERTENS ET AL.

Examiner

Mary K Zeman

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 1999.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-56 is/are pending in the application.
- 4a) Of the above claim(s) 52 and 54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49-51, 53, 55 and 56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☐ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 17) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other: _____

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DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit **1631**.

Claims 49-56 are pending in this application. Claims 52 and 54 have been withdrawn from consideration as being drawn to a non-elected species.

Applicant's arguments filed 12/2/99 have been fully considered but they are not completely persuasive..

In view of Applicant's arguments and/or amendments, the following objections or rejections are withdrawn:

The rejection of claims 49-51, 53 and 55-56 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

The rejection of claims 49-51, 53 and 55-56 under 35 U.S.C. 103(a) as being unpatentable over Bukh is withdrawn.

Claim Rejections - 35 USC § 112

Claims 49-51, 53 and 55-56 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons set forth in the previous office action..

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Applicant's arguments and supporting documents have been fully considered. Applicant asserts that HCV peptide vaccines, in fact, are useful as prophylactic vaccines, when they contain T cell stimulating epitopes. Applicant further argues that given the disclosures of Farci, Choo, Maertens, and Rosa, that one of skill in the art would recognize the workability of E1 or E2 peptide vaccines for HCV. These arguments have been fully considered, but are not persuasive.

As set forth previously, the specification is devoid of working examples demonstrating protection from viral challenge in a reasonable model system using the polypeptides of the invention. The area of protective vaccines, and the elicitation of protective immunity in HCV is highly unpredictable, as demonstrated by Farci (1997) and its contradictions with other art, such as the art cited by applicant.

Applicant submits Farci (1996) in support of his position. Farci (1996) vaccinated chimpanzees with polypeptides of E1. While some neutralizing antibodies were elicited to those peptides, escape mutants arose, and resulted in HCV infection of the animals. Further, Applicant has not indicated, or even suggested that the peptides of Farci (1996) are the same as, or similar to the peptides of the invention, nor is it clear that the peptides of Farci (1996) contain a T cell stimulating epitope, as required by the invention.

In regards to Choo et al (1994), Choo vaccinates the chimpanzees with full length E1/E2 complexes. The polypeptides of the invention are not full length, and determination of the elements required to match the results of Choo, using smaller peptides, is not predictable. And while Choo obtained protection in some animals, at least two animals became infected with HCV upon viral challenge. Applicant's polypeptides are quite different from the immunogens used by

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Choo et al, such that one cannot automatically draw the same conclusions for Applicant's polypeptides. It is entirely unclear whether the polypeptides of the invention would function in the same manner as full length E1/E2 complexes.

Rosa (1996) discloses a test which estimates the levels of neutralizing antibodies to particular polypeptides of HCV. Rosa uses full length E1, and a truncated E2 (aa384-715), which is still larger than the polypeptides of the invention. Rosa concludes that vaccination with certain proteins of HCV can correlate with the elicitation of neutralizing antibodies, that more than one epitope on E2 is required for these effects. Again, as the polypeptides of Rosa are significantly different than the polypeptides of the invention, one cannot automatically draw the same conclusions. It is not clear that the polypeptides of the invention possess both epitopes identified by Rosa as being important for the generation of neutralizing antibodies.

Applicant has submitted two abstracts by the inventors, describing vaccine experiments using purified E1 protein. These experiments appear to have used full length E1 protein, and not the shorter polypeptides of the invention, thus the conclusions of Maertens cannot immediately be applied to the polypeptides of the invention.

Diepolder (1997) submitted by Applicant, identifies a immunodominant polypeptide with T cell stimulating epitopes, however this epitope is not within E1 or E2, and Diepolder does not investigate vaccination and challenge experiments with that polypeptide.

Finally, Botarelli (1993) investigates the T cell stimulating ability of 6 recombinant HCV proteins. Botarelli uses full length E1 and E2 proteins, and is unable to draw solid conclusions as to their T cell stimulating ability in the patients sampled.

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Given the lack of success in the art, the lack of a correlation between the art and the invention, the lack of working examples in the specification, and the unpredictability of the generation of protective immunity, the specification, as filed, is not enabling for such vaccines.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The examiner can be reached between the hours of 7:30 am and 5:00 pm Monday through Thursday, and on alternate Fridays.

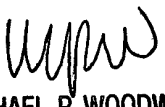
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308 4028.

The fax number for this Art Unit is (703) 305-7401.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

mkz
February 16, 2000


MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600